Weill Cornell Medicine
Office of Research Integrity

CornellResearch

HUMAN SUBJECT RESEARCH INTER-CAMPUS COLLABORATIONS

Background

Cornell University comprises several campuses, including the Ithaca-based campuses (Ithaca, Geneva and Cornell Tech campus, together, "Ithaca") and the Weill Cornell Medicine campuses (New York City and Doha, Qatar, together, "WCM"). The two sets of campuses operate under separate Federal Wide Assurances (FWAs) with the U. S. Department of Health and Human Services, and maintain separate research administrative offices (i.e. IRB, sponsored research, etc.) as part of each institution's human research protection program (HRPP). In addition, the Doha, Qatar campus maintains separate research administrative offices, but operates under the WCM New York City FWA.

For the purposes of this process document, "WCM" refers EXCLUSIVELY to the New York City campus.

An umbrella reliance agreement has been put in place between the IRBs at WCM and Ithaca to promote and enhance research involving human participants across Cornell's campuses and facilitate the timely, streamlined review of research collaborations spanning both campuses. A reliance agreement (also known as an IRB Authorization Agreement) is a document permitting, in this instance, either the WCM or Ithaca IRBs (the "Relying IRB") to cede review to the other campus's IRB (the "IRB of Record") for a particular study involving human participants. In this way, only one IRB reviews and approves human subject research activities for both campuses, avoiding duplicative review and regulatory oversight.

Each campus involved in the collaborative research is responsible for ensuring compliance with their campus's submission requirements for any required ancillary reviews, including but not limited to review by the respective campus's Institutional Biosafety Committee (IBC) and Radiation Safety group. Research staff from each campus must consult their own institutional policies to determine if additional requirements apply.

Process for Requesting Single IRB Review

A determination must be made on which campus's IRB should review and oversee the human research that will be undertaken. To facilitate this process, both the WCM and Ithaca IRBs will need to collect and review basic information about the planned collaboration. Either the WCM or the Ithaca Principal Investigator (PI) must send an email to both IRBs containing the following information:

- To: irbhp@cornell.edu; irb@med.cornell.edu
- CC: PI from collaborating campus
- Subject: WCM-Ithaca Collaboration Request [Name of WCM PI/Name of Ithaca PI]
- Body:
    - "[PI Name] from WCM and [PI Name] from the Ithaca campus plan to collaborate on research involving human subjects. We request that the [WCM IRB / Ithaca IRB] serve as the IRB of record."
      The last sentence should only be included if the PIs have a preference for which IRB will review the project
    - Project name
    - Indicate whether (and where) biomedical procedures will take place, including location of informed consent procedures
    - Briefly describe any data/specimen collection, including location where this will occur (*Example: Blood samples will be collected at WCM)*
    - Briefly describe the role/involvement of the other campus (*Example: Ithaca investigators will receive and analyze the de-identified samples)*
    - State whether the project involves use of HIPAA-protected data
    - Target research population, especially if students are research subjects
    - Any other relevant information not captured above

Staff from the WCM and Ithaca IRBs will jointly determine which campus will serve as the IRB of record for any given collaboration. This determination will be made within 10 business days of receipt of the request. The campus chosen as the IRB of record will reply to the email thread to announce the decision and describe next steps (as set forth in this document, below). In determining which campus's IRB should complete the review, WCM and Ithaca IRB staff will be guided by the general principles described below.

I. Review procedures when WCM is chosen as the IRB of record

WCM's IRB will typically serve as the IRB of record when collaborative human subjects research involves investigators from both campuses and:

- involves biomedical procedures or sampling;
- involves use or analysis of data that may be protected under HIPAA*;
- data collection will take place primarily at WCM; or
- the study meets the NIH definition of a clinical trial.

Ithaca is not a HIPAA-covered entity and therefore cannot receive and store private or protected health information, as defined under the privacy rule.

Example Scenario

Ithaca investigator and WCM investigator are conducting research using tissue samples. Samples will be collected from patients at WCM. The identifiable samples will be shared with Ithaca. Both campus's investigators will receive scholarly recognition on all publications related to the study's findings.

Decision: WCM would likely be chosen to serve as the IRB of record for this intercampus collaboration, because human tissue collection will occur at WCM, and WCM has the relevant expertise to review biomedical research.

WCM Investigator Responsibilities

Following a determination that WCM will act as the IRB of record for a particular intercampus collaboration, the WCM PI must complete the typical WCM IRB application using WCM's online protocol management system, WRG-HS, according to the guidance and directions of the WCM IRB. The form can be accessed here: wrg.weill.cornell.edu. Because a WCM "CWID" is required to access WRG-HS, the WCM investigator must submit all application materials to the WCM IRB, even in cases where the overall project PI is based in Ithaca. As part of the IRB application submission, a copy of the email announcing the decision that the WCM IRB will be the IRB of Record for the study must also be included.

The PI will also provide a list of external investigators who will act as research personnel on the study as part of the application. This can be a Word or PDF document listing all non-WCM personnel, including any Ithaca-based investigators, and listing their respective roles and responsibilities on the study, their email addresses, and noting their Ithaca affiliation.

Ithaca Investigator Responsibilities

All Ithaca personnel on the list of external investigators provided by the WCM IRB must complete an SSR (Study Specific Report) form disclosing their financial interests. These forms should be submitted to the WCM IRB with the application. The form can be downloaded at: https://research.weill.cornell.edu/compliance-integrity/conflicts-management-office.
When WCM is the IRB of record, WCM's policies concerning required training will apply, found here: https://research.weill.cornell.edu/compliance-integrity/wcm-institutional-review-board/irb-human-subjects-training-requirements.
Unlike Ithaca, WCM requires personnel on all human subject protocols to complete training in Good Clinical Practices, in addition to human subjects training. Ithaca investigators will need to provide WCM's IRB with proof that they have completed these required trainings. Completion certificates must be attached in the personnel section of the IRB application.

In addition, if Ithaca investigators will be conducting research procedures in WCM/NewYork-Presbyterian clinical space additional requirements must be met, including but not limited to HIPAA training, medical clearance, etc.

While awaiting approval by the WCM IRB, the collaborating PI at Ithaca must complete the Ithaca IRB's three-page "Abbreviated Application Form" available here: https://researchservices.cornell.edu/forms/irb-authorization-agreement. This document provides the Ithaca IRB with summary information about the project, and details the specific roles and responsibilities of the Ithaca-based investigators.

Following approval, any reportable events (expected, unexpected or deviations) relating to the study should be reported to the WCM IRB, regardless of the campus affiliation of the investigators involved.

The Ithaca IRB reserves the right to place enrollment on hold, suspend or terminate the research activity or request additional protections at any Ithaca-based campus study site at any time. At such time, the Ithaca IRB or Ithaca Institutional Official will promptly notify the WCM IRB of these actions.

II. Review procedures when Ithaca is chosen as the IRB of record

Ithaca's IRB will typically serve as the IRB of record when collaborative human subjects research involves investigators from both campuses and:

- the study involves social/behavioral/educational research (SBER); or
- data collection will take place primarily at the Ithaca campuses.

Example Scenario

Ithaca investigator and WCM investigator are conducting research about stress in college students. Both investigators will recruit participants from their respective campuses. The respective campus study teams will consent and interview participants. The data from each site will be coded and shared between sites for data analysis. Both sites' investigators will receive scholarly recognition on all publications related to the study's findings.

> Decision: Ithaca would likely be chosen to act as the IRB of record for this intercampus collaboration. Although data collection will occur on both sites, Ithaca's IRB has the relevant expertise to review SBER research.

Ithaca Investigator Responsibilities

Following a determination that Ithaca will act as the IRB of record for a particular intercampus collaboration, the Ithaca PI must complete the Ithaca IRB's New Protocol Application form, which can be downloaded at: https://researchservices.cornell.edu/forms/irb-new-protocol-application-form. As part of the protocol submission, along with a completed application form and supporting materials, a copy of the email announcing the decision that the Ithaca IRB will be the IRB of Record for the study must also be included. In Section 1.5.3 of the New Protocol Application form, the names and other relevant information about the WCM investigators involved in the study will be listed. When Ithaca is the IRB of record, Ithaca's policies concerning required training will apply, as described here: https://researchservices.cornell.edu/resources/irb-training. Please provide completion certificates for the WCM investigators to show that required human subjects training has been completed. In addition, if Ithaca investigators will be conducting research procedures in WCM/NewYork-Presbyterian clinical space additional requirements must be met, including but not limited to HIPAA training, medical clearance, etc.

WCM Investigator Responsibilities

While waiting for approval of the Ithaca IRB, the collaborating PI at WCM must complete the WCM IRB's "External IRB Application" in WRG-HS. In particular, please ensure the following are completed on a timely basis:

1. Ancillary reviews (e.g. IBC, RSC, pathology, etc.), if applicable
2. Training (human subjects training, GCP and COI modules)
3. Conflict of Interest (COI) disclosures

The Ithaca IRB must approve the research and the WCM IRB must acknowledge the Ithaca IRB approval before any research activities at the WCM site may begin. The WCM IRB will acknowledge the approval of the Ithaca IRB once it has certified that all local research context requirements are met, including all local training and conflict of interest requirements.

In general, the WCM IRB will not require changes to the model consent approved by the Ithaca IRB; however, the WCM IRB may require an addendum to the consent, which would also need to be approved by the Ithaca IRB.

The Ithaca IRB does not serve as a Privacy Board under the HIPAA regulations; therefore, it will not be able to approve HIPAA authorizations or HIPAA waivers. The WCM IRB (which does serve as a Privacy Board) must approve any HIPAA documents.

The expiration date of the IRB approval will be determined by the Ithaca IRB. If the WCM IRB receives a notice of continuing review approval and all of the investigators have not completed their local training or conflict of interest requirements, the delinquent investigators will not be able participate in the research until they have met all of the requirements in question.

All reportable events must be reported to the WCM and Ithaca IRBs. WCM reserves the right to place enrollment on hold, suspend or terminate the research activity, or request additional protections at the WCM site at any time. At such time, the WCMC IRB or Institutional Official will promptly notify the Ithaca IRB of these actions; however, the PI may also be required to notify the Ithaca IRB, within the Ithaca IRB's specified reporting deadlines.

The WCM IRB reserves the right to place enrollment on hold, suspend or terminate the research activity or request additional protections at any Ithaca-based campus study site at any time. At such time, the WCM IRB or WCM Institutional Official will promptly notify the Ithaca IRB of these actions.

Further Information

If you have questions about intercampus collaboration on human subjects research that are not addressed in this document, or wish to discuss a particular project, please contact the following IRB representatives:

Ithaca IRB:

Guilaine D. Senecal, JD
Assistant Director
Office of Research Integrity and Assurance
(607) 255 – 8994
gds64@cornell.edu
https://researchservices.cornell.edu/compliance/human-research

WCM IRB:

Angela Cartmell-McGlyn, PhD, CIP
Assistant Director, IRB Operations
Human Research Protection & Compliance
Office of Research Integrity
(646) 962 – 7068
anc2267@med.cornell.edu
https://research.weill.cornell.edu/compliance-integrity/institutional-review-board